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A randomised controlled trial investigating the effect of POSition IN LABour and effect on pudendal nerve physiology

Submission date	Recruitment status	[ ] Prospectively registered
15/01/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/05/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/10/2014	Pregnancy and Childbirth	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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2

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title

Acronym
POSINLAB

Study objectives
The hypothesis of the trial is that direct pressure on the pudendal nerve and or sacral plexus during the first stage of labour rather than traction on the pelvic floor during the second stage of labour is supported by previous observations of our research group. Firstly pudendal nerve latency has been consistently shown to be prolonged more on the left than on the right. Secondly caesarean delivery late in labour does not prevent changes in pudendal nerve terminal motor latency.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committe of the National Maternity Hospital, 12/09/2002.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pudendal nerve neuropathy

Interventions
It is proposed to randomise sixty primparous women in the first stage of labour to conventional nursing on the left side or nursing on alternate sides every 30 minutes. Delivery would be in the left lateral position in group one and in the lithotomy positon in group two.

Pelvic floor Electromyography (EMG), anorectal manometry and continence scoring would be performed at the six week postnatal check.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The effects on pudendal nerve motor latency

Secondary outcome measures
The difference in anaorectal manometry and continence scoring between the groups

Overall study start date
01/02/2007

Completion date
30/06/2007

Eligibility

Key inclusion criteria
Primiparous healthy patients who are in labour with a single cephalic foetus

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
60

Key exclusion criteria
1. Patients with a history of bowel symptoms or bowel surgery
2. Patients without fluent English
3. Diabetic patients
4. Patients attending the hospital High Risk Clinic

Date of first enrolment
01/02/2007

Date of final enrolment
30/06/2007

Locations

Countries of recruitment
Ireland

Study participating centre
UCD School of Medicine and Medical Science
Dublin
Ireland
2

Sponsor information

Organisation
Health Research Board of Ireland (Ireland)

Sponsor details
73 Lower Baggot Street
Dublin
Ireland
2

Sponsor type
Government

Website
http://www.hrb.ie/

ROR
https://ror.org/003hb2249

Funder(s)

Funder type
Government

Funder Name
Health Research Board of Ireland (Ireland)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration